UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF INDIANA

TONY BROWN , **Plaintiff,** **v.** **ZIMMER BIOMET HOLDINGS, INC., f/k/a ZIMMER HOLDINGS, INC.; ZIMMER BIOMET, INC., f/k/a ZIMMER, INC.; and ZIMMER BIOMET U.S., INC.,** **Defendants.**	**CASE NO.** 3:20-cv-561 **JURY TRIAL DEMANDED**

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiff Tony Brown ("Plaintiff"), by his undersigned counsel, bring this Complaint against Defendants Zimmer Holdings, Inc. and Zimmer, Inc., (hereinafter collectively "Zimmer" and/or "Defendants"), and allege:

INTRODUCTION

1. This product liability action relates to the design, development, manufacture, testing marketing, promotion, distribution, and sale of Zimmer's defective hip implant component known as the Durom Acetabular Component (the "Durom Cup").

2. The Durom Cup was surgically implanted in Plaintiff Tony Brown on September 25, 2008, and required surgical revision on July 1st, 2019, because the Durom Cup was defective and failed. These multiple surgeries caused Plaintiff Tony Brown to suffer significant injuries, including great pain and agony that restricted his ability to engage in the physical activities he enjoys, and has affected his ability to perform his basic household chores.

3. Zimmer, founded in 1927, is one of the leading competitors in the U.S. hip and knee replacement market and accounted for seventy percent of the market in 2008.

4. In 2008, the U.S. hip and knee replacement market was valued at $6.7 billion dollars, with the hip replacement market contributing thirty-eight percent of the market at roughly $2.5 billion dollars. According to Zimmer's 2008 Annual O-K Report, Zimmer was number one in global market share for reconstructive hip components. In the period ending December 2008, Zimmer reported $1,279.5 million in hip component sales. Zimmer's total 2008 sales exceeded $4 billion.

5. Zimmer designs, develops, manufactures, markets, tests, distributes and sells reconstructive orthopedic implants, including joint, dental and spinal implants, trauma products and related orthopedic surgical products. Zimmer's related orthopedic surgical products include surgical supplies and instruments designed to aid in orthopedic surgical procedures.

6. Zimmer's Durom Cup is an orthopedic device used in total hip replacement surgeries. Hip replacement surgery, also known as hip arthroplasty, is a surgical procedure in which the patient's hip joint is resurfaced and replaced with an artificial implant. It is typically used to repair joint/bone damage or to treat arthritis pain in the hip joint area. The hip joint is in essence a large ball-and-socket joint composed of two parts: the head of the thighbone, or femur; and the acetabulum, a cup-shaped bone in the pelvis. Therefore, hip replacement surgery traditionally consists of two tasks: (1) replacing the end of the femur, or thighbone, with an artificial "ball," typically made of metal or stainless steel; and (2) resurfacing the hip socket using a metal shell and plastic liner, into which the ball attached to the femur will fit.

7. During hip replacement surgery, damaged portions of the hip are replaced with smooth, durable artificial surfaces to allow the joint to function properly. The Durom Cup is not

cemented or screwed in place during implantation. Instead, it was designed to bond to the patient's hip bone.

8. The outside of the Durom Cup is porous, and has been sprayed with a highly engineered substance (a titanium plasma-sprayed coating) that is intended to facilitate the cup's acceptance by the human body. It is intended that the patient's own bone will grow into the exterior shell of the cup to hold the cup in place.

9. Rather than functioning in the intended manner, the Durom Cup implant resists bone growth and, as a result, instead of adhering to the bone, it comes loose and/or pops free from the hip, which can cause damage to the pelvic bone. This unintended result also causes extreme and devastating pain to the patient and necessitates revision surgery to remove the failed Durom Cup and replace it with a product that functions properly.

10. The Durom Cup is part of a metal-on-metal hip implant system, which was widely marketed by Zimmer as being more durable.

11. According to an article published in the *New York Times* on Thursday March 4, 2010, entitled "Concern Over Metal-on-Metal Implants," "studies in recent years indicate that in some cases the devices can quickly begin to wear, generating high volumes of metallic debris that is absorbed into a patient's body. That situation can touch off inflammatory reactions that cause pain in the groin, death of tissue in the hip joint and loss of surrounding bone." Plaintiff Tony Brown, like other patients in the studies, likely suffered from metal debris causing death to the soft tissue and bone surrounding his hip, and further decreasing his chances for a successful second hip replacement.

12. The suspension of sales of Zimmer's Durom Cup was announced by Zimmer on July 22, 2008. The defects in the Durom Cup have affected and will continue to affect in the

future, thousands of patients who had Durom Cups implanted in their hips. The Durom Cup has been implanted in over 12,000 patients in the United States since it was first sold on the U.S. market in 2006.

13. When introducing the Durom Cup, Zimmer represented to consumers and their physicians that the Durom Cup would provide greater range of motion and less wear on the bearing than traditional hip replacement implant components, thus making it an ideal product for younger, active patients. Contrary to Zimmer's representations, the Durom Cup is prone to an unprecedented failure rate for hip replacement implant components.

14. Since Defendants first began selling the Durom Cup in the United States in 2006 through on or about July 22, 2008, the product labeling and product information for the Durom Cup failed to contain adequate information, instructions, and warnings concerning implantation of the product and the risks that the Durom Cup can loosen and separate from the acetabulum (hip socket) in patients.

15. Despite their knowledge of the defects and serious injuries associated with use of the Durom Cup, Defendants engaged in a marketing and advertising program which, as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the Durom Cup was safe and effective.

16. At all relevant times, Zimmer knew or should have known that the Durom Cup was not safe for the patients in whom it was implanted, including Plaintiff Tony Brown, because of the unacceptable failure rate, which is approximately 24%, according to one leading hip surgeon.

17. On information and belief, the failure rate, to date, ofDurom Cups implanted in the United States is between 20% and 30%. Since the Durom Cups often fail many months or

even sometimes a year or more after the initial surgery, and are continuing to fail in patients, the true failure rate will likely be much higher, as more and more of these devices are failing in patients over time.

18. Notwithstanding the knowledge of predicted failures with the defective Durom Cup, Zimmer continued to sell the Durom Cup for implantation in patients until July 22, 2008, when Zimmer announced a suspension of the sale and distribution of the Durom Cup.

19. Plaintiff Tony Brown, and other patients in whom the Durom Cups were implanted, have suffered not only physical injuries, but they also bear an unacceptable increase in the risk of severe pain and disability, with or without a costly and painful revision surgery. The revision surgery is invasive and painful and is often needed to replace the defective Durom Cup implant, as it was here.

JURISDICTION AND VENUE

20. Tony Brown is a citizen of the State of Louisiana, residing in Tangipahoa County, Louisiana.

21. Zimmer Biomet Holdings, Inc., formerly known as Zimmer Holdings, Inc., is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Indiana. At all times relevant to this action, Zimmer Biomet Holdings, Inc. was the publicly traded holding company with wholly owned subsidiaries that it controlled which tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/ or sold the Zimmer Hip System in interstate commerce and throughout the State of Louisiana, and generated substantial revenue as a result.

22. Zimmer Biomet, Inc. formerly known as Zimmer, Inc., is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Indiana. At all times relevant to this action, Zimmer Biomet, Inc. was a wholly-owned subsidiary of Zimmer Biomet Holdings, Inc. On April 24, 2014, Zimmer Holdings, Inc. entered into an agreement to merge with LVB Acquisition, Inc., the parent company of Biomet, Inc. After the merger, Zimmer Holdings, Inc. was renamed Zimmer Biomet Holdings, Inc. and Zimmer, Inc. was renamed Zimmer Biomet, Inc. At all times relevant to this action, Zimmer Biomet, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System in interstate commerce and throughout the State of Louisiana and generated substantial revenue as a result.

23. Zimmer Biomet U.S., Inc., formerly known as Zimmer U.S., Inc., is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Indiana. At all times relevant to this action, Zimmer Biomet U.S., Inc. was a wholly owned subsidiary of Zimmer Biomet, Inc. At all times relevant to this action, Zimmer Biomet U.S., Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System in interstate commerce and throughout the State of Louisiana and generated substantial revenue as a result.

24. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000.00 exclusive of interest and costs.

29. Venue in this action properly lies in the Northern District of Indiana where Defendants have their principle place of business.

FACTUAL ALLEGATIONS

1. BACKGROUND ON ARTIFICIAL HIPS AND HIP REPLACEMENT DEVICES

25. The human hip joint consists of two parts: a ball and a socket. A portion of the pelvic bone forms a cup-shaped socket; the ball at the top of the thigh bone fits into it. The ball is surrounded with cartilage which, in a healthy hip joint, allows the ball to move smoothly within the socket. Conditions such as osteoarthritis and avascular necrosis can cause degeneration of the hip joint such that hip replacement is required. A hip implant is designed to replicate the human anatomy- that is, the relatively simple ball and socket structure of the human hip joint. Total hip replacement surgery involves implanting an artificial ball and socket into the patient.

26. The artificial hip implantation process requires a surgeon to insert an artificial cup with a smooth lining into the patient's diseased pelvic socket. The lining serves the same purpose as natural cartilage: allowing for smooth movement of the ball portion of the thigh bone. The diseased or degenerated ball part of the thigh bone is then removed and replaced by a metal or sometimes ceramic ball mounted onto a thin metal stem. The metal stem is then fitted into the thigh bone. Finally, the ball is placed securely into the pelvic socket that has been fitted with the artificial metal cup, where it should move easily, without friction or pain to the patient.

27. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications include rheumatoid arthritis, avascular necrosis, traumatic arthritis, protrusion acetabuli, certain hip fractures, benign and malignant bone tumors, arthritis associated with Paget's disease of the bone, ankylosing spondylitis and juvenile rheumatoid arthritis. The aims of the procedure are pain relief and improvement in hip function. Hip replacement is usually considered only once other therapies, such as pain medications, have failed.

28. Total hip arthroplasty ("THA"), or total hip replacement, is a common medical procedure performed on more than 420,000 patients in the U.S. each year. It is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma. Traditional devices to replace degenerative hips utilize implantable metal or ceramic heads fitting into a modular metal-backed polyethylene bearing. One concern that historically plagues successful THAs is the wear of the bearing. As the THA becomes more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear. The Durom Cup promised to offer an alternative surface that would resist wear and tear

29. The Durom Cup is a monoblock (constructed of a single piece of material) cup made of cobalt chromium (CoCr) alloy and is designed for use in combination with Zimmer's Metasul Metal-on-Metal Tribological Solution LDH (Large Diameter Heads) for THA. The design and material of the Durom Cup are key elements to its intended stability, wear resistance, and intended bone sparing characteristics. The Durom Cup has a pure titanium plasma-sprayed coating for fixation. The coating on the Durom Cup sold in the United States has a different structure and is slightly thicker (0.1 mm) compared to the same products which were sold for use in patients outside of the United States.

HISTORY OF THE DUROM CUP

30. The Durom Cup was launched in Europe in 2003 for hip resurfacing procedures. Hip resurfacing requires less bone removal than conventional THA, but necessitates a different surgical technique. The Durom Cup was made available in Canada and Australia in 2003, India and Korea in 2005, and Argentina in 2006.

31. On or about December 19, 2005, Zimmer submitted a section 51 O(k) Premarket Notification of Intent (K053536) to the FDA to manufacture and market the Durom Acetabular Component and the Metasul LDH (Large Diameter Heads) devices to the public. Three months later, on March 19, 2006, the FDA cleared the device for marketing and distribution in the United States.

32. The 510(k) approval process by the FDA is regarded as a simplified “me too" application process, which does not require extensive review and approval by the FDA. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval. Submitters simply must compare their device to one or more legally marketed devices (devices marketed prior to May 28, 1976) and make and support their substantial equivalency claims. The FDA does not perform 510(k) pre-clearance facility inspections and submitters may market the device immediately after 510(k) clearance is granted

33. In this instance, Zimmer submitted a simplified 51 O(k) application that compared the Durom Cup to earlier products called "predicate devices" manufactured by competitors. In its application, Zimmer described: "The proposed device has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices."

34. No clinical studies were conducted in connection with the submission of the application for the Durom Cup. As part of the application process, Defendants stated that the "results of non-clinical analysis demonstrate that the device is safe and effective and substantially equivalent to the predicate device (as implants)." Further in their submission to the FDA the Defendants repeat throughout that the Durom Cup is intended to be a device that is simply

similar to previously approved predicate devices. Therefore, the FDA was persuaded by Defendants that any additional review and investigation was unnecessary.

DESIGN & MANUFACTURE OF THE DUROM CUP

35. Zimmer's Durom Cup is a flattened hemisphere, which is meant to offer a greater range and freedom of movement. With a constant wall thickness of 4 mm throughout all sizes, the cup maintains an inner diameter as large as possible, while intended to maintain maximum implant strength and minimum bone resection of acetabular bone mass. A coating of pure titanium using a plasma spray under vacuum and static load is applied to the outer surface, called Porolock (tm) Ti VPS. The high carbon cobalt chromium (CoCr) alloy is produced by a forging rather than casting process. This means that the size of block carbides is up to eight-times smaller compared to cast cobalt chromium (CoCr) prostheses. The resulting lower surface roughness was intended to lead to a lower wear rate when compared with cast cobalt chromium (CoCr) alloys.

36. Zimmer failed to recognize the deficiencies of the Durom Cup due to poor and inadequate quality assurance procedures, including failure of Zimmer to implement appropriate physical, manual, x-ray, microscopic and other inspections of the Durom Cup. Zimmer failed to implement or utilize adequate safeguards, tests, inspections, monitoring and quality assessments to ensure safety of the defective device. At the time the devices were manufactured and sold to patients, the devices were defectively manufactured and unreasonably dangerous, and did not conform to the federal regulations subjecting patients to risks of injury.

37. During the time Zimmer manufactured the Durom Cup, inadequate manufacturing processes led to material flaws in the quality systems at its manufacturing facilities.

38. During the course of manufacturing the Durom Cup, Zimmer failed in several ways, including, without limitation, by:

(a) failing to conduct adequate mechanical testing on components, subassemblies and/or finished Durom Cup;

(b) failing to test an adequate number of sample devices on an ongoing basis;

(c) failing to take adequate steps to specifically identify failure modes with clarity and suggest methods to monitor, avoid, and/or prevent further failures;

(d) failing to identify and/or note the significance of any testing that resulted in failure of the Durom Cup;

(e) failing to take corrective actions to eliminate or minimize further failures ofthe Durom Cup;

(f) failing to adequately explain performance specifications for the components, subassemblies, and finished Durom Cup;

(g) failing to adequately explain or justify all test conditions and acceptance criteria for the Durom Cup;

(h) failing to perform adequate testing in an environment that adequately simulated in vivo conditions; and, by

(i) failing to perform adequate quality assurance testing before and after sterilization.

39. Zimmer failed to perform adequate testing of the Durom Cup, including its components and subassemblies, to ensure that the Durom Cup functioned properly during and after implantation.

40. As a result of these manufacturing and quality control problems associated with the manufacture of the Durom Cup, the component was inadequately and defectively manufactured making it adulterated, and outside of the specifications expressly approved by the FDA.

DUROM CUP DEFECTS ARE EXPOSED BY LEADING PHYSICIANS

41. After the FDA initially approved the 510(k) application, Zimmer began to aggressively market the Durom Cup to physicians and their patients.

42. Relying upon Zimmer's representations, physicians began using broadly the Durom Cup instead of other models. Reports of Durom Cup failures soon followed. It is now apparent that a significant percentage of the Durom Cups have failed, and that the failure rate is unacceptably high.

43. The failure rate is estimated at upwards of 24% (twenty-four percent) when analyzing patients over a four-year period (2006-2010). This failure rate is much higher than similar products made by Zimmer, and is also much higher than the failure rate of competitor's devices. Furthermore, this rate is four times Zimmer's predicted failure rate of 5.7% Lawrence Dorr, M.D., a world-renowned orthopedic surgeon and Zimmer consultant, and a team of doctors at The Arthritis Institute at Good Samaritan Hospital in Los Angeles, California, have recently published the results of their study comparing one hundred and eighty patients who had the large-diameter (44- to 50-mm) Durom Cup and fifty-four patients who had a small-diameter (28-mm Metasul®) articulation implanted between May 2006 and November 2007. The total

number of clinical failures was forty-one of one hundred and eighty patients (23%). Twenty-eight of one hundred and fiftyone patients had radiographic impending failure at final follow-up (18.5%). All post-revision surgery retrieved cups were examined in detail and had no evidence of bone on the taxation surface.

44. Since at least 2007, surgeons implanting the Durom Cup complained to Zimmer that the device was failing in their patients, many of whom had to undergo painful, invasive and expensive revision surgeries.

45. One of these surgeons was Dr. Dorr, who warned Zimmer in 2007 of the high rate of Durom Cup failures. At the time Dr. Dorr warned Zimmer of the high rate of failures, he was a paid Zimmer consultant and a veteran of thousands of hip replacement surgeries.

46. In particular, Dr. Dorr informed Zimmer that x-rays showed that the Durom Cup was failing because it was separating or loosening from the bone, rather than fusing to it, causing patients crippling pain while the metal cup moved around the hip socket and rubbed against the bone.

47. Zimmer ignored Dr. Dorr's warnings and continued to sell the Durom Cup.

48. In April 2008, Dr. Dorr publicly warned other orthopedists about the cup failures his patients were experiencing and urged Zimmer to stop selling the Durom Cup.

49. After informing colleagues about his experience with the Durom Cup, Dr. Dorr heard from several other doctors who reported similar problems. According to Dr. Dorr and other physicians, x-rays of patients who received defective Durom Cups showed that the socket was separating from bone, rather than fusing with it.

50. Despite this memorandum, Zimmer again ignored the warnings and continued to sell the Durom Cup.

51. In late May 2008, Zimmer finally informed surgeons that it was investigating Dr. Dorr' s complaint but that it was not suspending sales as Dr. Dorr had recommended. While Zimmer investigated complaints, roughly 1300 more patients were implanted with the Durom Cup in the United States. Zimmer responded by defending the Durom Cup and blaming the doctors' implantation techniques. Zimmer later attributed failures of the Durom Cup to a discrepancy in doctors' techniques in performing THA surgeries. Zimmer contended (and still apparently contends) that the technology and design parameters of the Durom Cup demand a surgical technique with "high precision and specificity compared to more common and familiar hip arthroplasty surgical techniques practiced in the U.S." Therefore, according to Zimmer, the Durom Cup requires additional training in implantation technique and cup placement for many surgeons who use the device and who may otherwise be experts in THA.

52. Around this time, although Zimmer still maintained that there were no issues with the Durom Cup, other doctors began to stop implanting them. Even still, Zimmer continued to market the Durom Cup to unsuspecting physicians and patients, selling hundreds of units between May 2008 and July 22, 2008.

53. Throughout 2008, while the Durom Cup was being implanted in patients across the United States and around the world, Zimmer was accumulating mounting and overwhelming reports that the Durom Cups were failing at an alarming rate. Zimmer failed to disclose to physicians and patients the true failure rate.

TEMPORARY SUSPENSION OF THE DUROM CUP

54. Zimmer continued to sell the Durom Cup for implantation in patients until July 22, 2008, when Zimmer announced it was temporarily suspending Durom Cup marketing and distribution in the United States. In its announcement, Zimmer stated that the

suspension was necessary "while the Company updated labeling to provide more detailed surgical technique instructions to surgeons and implements its surgical training program in the U.S.

55. Zimmer announced that the company was taking this "voluntary action to address its concerns regarding reports of cup loosening and revisions of the acetabular component used in total hip replacement procedures" but that Zimmer "has found no evidence of a defect in the materials, manufacture, or design of the implant."

ZIMMER'S IMPROPER FAILURE TO RECALL THE DUROM CUP

1. Under federal regulations, a recall is "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." A recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the FDA.

2. These sections also recognize that recall is an alternative to an FDA-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the FDA to monitor recalls and assess the adequacy of a firm's efforts in recall. A company's voluntary recall of a medical device and the FDA's classification of that action as a Class I recall establish that the device violates FDA regulations.

58. To date, Zimmer has not issued a public recall of the Durom Cup and instead has described its action as only a "temporary suspension" of the device. In reality, Zimmer has made the device "unavailable for purchase in the United States," (see screen shot from Zimmer e-catalog as published on Zimmer's website on February 23, 2010, attached as

Exhibit A to this Complaint), but has not voluntarily recalled the device.

PLAINTIFF' INJURIES DUE TO THE DEFECTIVE DUROM CUP

59. Plaintiff Tony Brown, a 60-year-old resident of Tangipahoa Parish, Louisiana, has been significantly injured as a result of the implantation of the Durom Cup in Plaintiff Tony Brown's right hip. As a result of the Durom Cup's failure, Tony Brown has had to adjust his life to accommodate the ongoing injuries.

60. The defective Durom Cup limited Plaintiff Tony Brown's activities because he suffered from pain likely caused by the loosened Zimmer System.

61. Additionally, Plaintiff was tested on October 25, 2017 for levels of metal ions. The results showed levels of Chromium and Cobalt far exceeding the normal range, which is a direct effect of the faulty Zimmer Durom cup metal-on-metal design described above which can result in metallosis.

62. The pain persisted until Plaintiff Tony Brown underwent a revision surgery on July 1, 2019 at St. Tammany Parish Hospital in Covington, Louisiana. Plaintiff's revision surgery necessitated a three-day hospitalization and weeks of physical therapy. Dr. Roderick Chandler, Jr., the surgeon who conducted Plaintiff's revision surgery, noted in his operative report that he "actually saw the cup move" which likely indicated the Zimmer parts were "at least somewhat loose."

63. In reliance on Zimmer's marketing of the Durom Cup, Plaintiff Tony Brown and his physician expected that this device would provide him with better stability and range of motion than other hip replacement devices on the market, and that the device would be resistant to wear, making it ideal for very active individuals such as Tony.

64. In addition, Tony and his physician believed that the Durom Cup should last Tony at least twenty years. Tony expected a significant improvement in his quality of life after the initial hip replacement surgery, which did not occur and continues to impact him emotionally and physically.

CLAIMS FOR RELIEF
COUNT I
(Strict Liability- Failure To Warn And Instruct)

65. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

66. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Durom Cup. Defendants designed, manufactured, assembled and sold the Durom Cup to medical professionals and patients knowing that they would then be implanted in patients in need of hip prosthesis.

67. Defendants distributed and sold the Durom Cup in the condition in which it left its place of manufacture, in its original form of manufacture, which included the defects described herein. The Durom Cup was expected to and did reach Plaintiff Tony Brown without substantial change or adjustment in its condition as manufactured and sold by Defendants.

68. The Durom Cup designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendants was in a dangerous and defective condition and posed a threat to any user or consumer of the Durom Cup. Plaintiff Tony Brown was and is in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of the Durom Cup.

86. The Durom Cup was implanted and used in the manner for which it was

intended. This use has resulted in severe physical and emotional and other injuries to Plaintiff.

69. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the Durom Cup created a high risk of bodily injury and serious harm.

70. Defendants tailed to provide adequate and timely warnings or instructions regarding the Durom Cup and its known or knowable defects. Defendants failed to advise patients like Tony Brown that monitoring of the cup was necessary to avoid long and painful periods during which the device failure would go undetected - as it did here.

71. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Tony Brown has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct result, Plaintiff expended money and will continue to expend money for medical bills and expenses. Plaintiff are entitled to compensatory damages in an amount to be proven at trial.

COUNT II
(Strict Liability- Design Defect)

72. Plaintiff incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

73. Zimmer is the manufacturer and/or supplier of the Durom Cup and placed this device into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the Durom Cup.

74. The Durom Cup manufactured, marketed, distributed and/or supplied by Zimmer was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

75. The Durom Cup was expected to and did reach Plaintiff Tony Brown without substantial change in condition. Alternatively, the Durom Cup manufactured and/or supplied by Defendants was defective in design or formulation, because when the Durom Cup device left the hands of Defendants, the manufacturers and/or suppliers, the Durom Cup was unreasonably dangerous and more dangerous than an ordinary consumer would expect.

76. The Durom Cup was designed and/or manufactured in a manner violative ofthe Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.,* and the Medical Devices Amendment thereto (hereafter "FDCA"). The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the Durom Cup were not in conformity with applicable requirements of the FDCA.

77. The Durom Cup manufactured and/or supplied by Zimmer was defective due to inadequate warnings and/or inadequate trials, testing and study, inadequate exposure of the real risks inherent with the device as determined by the clinical trials, and inadequate reporting of the results of the clinical trials and post-marketing clinical experiences with the device.

78. The Durom Cup manufactured and/or supplied by Zimmer was defective due to inadequate post-marketing warnings or instructions because, after Zimmer knew or had reason to know of the risk of injury from the Durom Cup, it failed to provide adequate warnings to the medical community, patients, and the public, including Plaintiff, and continued to promote and advertise the Durom Cup as safe and effective.

79. The Durom Cup was designed, manufactured, distributed, tested, sold, marketed, and advertised defectively by Zimmer. As a direct and proximate cause of Zimmer's defective design of the Durom Cup, Plaintiff Tony Brown and other patients had the device implanted in their bodies, and suffered and will continue to suffer increased risk of long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery, and pain and suffering.

80. Zimmer was or should have been in possession of evidence demonstrating that the Durom Cup caused serious injuries and would fail. Nevertheless, Zimmer continued to market the device by providing false and misleading information with regard to the safety and efficacy of the Durom Cup.

81. Zimmer's actions, as described above, were performed willfully, intentionally and with reckless disregard for the rights of Plaintiff, other patients and the public.

82. As a result of Zimmer's conduct, Plaintiff suffered the losses, injuries and damages specified herein.

COUNT III
(Strict Liability -Manufacturing Defect and Failure to Adhere to Quality Controls)

83. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

84. The Durom Cup is defectively manufactured because the foreseeable risks of mechanical malfunction and failure outweigh the benefits associated with the Durom Cup.

85. The Durom Cup was designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.,* and the Medical Devices Amendment thereto (hereafter "FDCA"). The facilities or controls used by Defendants in the

manufacture, packing, storage, or installation of the Durom Cup were not in conformity with applicable requirements of the FDCA.

86. The Durom Cup was expected to and did reach the Plaintiff Tony Brown without substantial change or adjustment to its mechanical function.

87. Defendants knew or should have known ofthe manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the Durom Cup.

88. Furthermore, the Durom Cup and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

89. The Durom Cup was defective due to inadequate warnings or instruction because Defendants knew or should have known that the Durom Cup created a high risk of bodily injury and serious harm. Defendants failed to adequately and timely warn consumers of this risk.

90. The Durom Cup is inherently dangerous for its intended use due to a manufacturing defect or defects and improper functioning. Defendants are therefore strictly liable to Plaintiff for their breach of duty to Plaintiff.

91. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Tony Brown has sustained and will continue to sustain severe physical injuries, and Plaintiff have suffered and will continue to suffer severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial.

COUNT IV
(Negligence)

92. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

93. At all relevant times, Defendants had a duty and continue to owe a duty to Plaintiff to provide a safely manufactured product, to notify the FDA of flaws, and to warn the FDA and Plaintiff of the defective nature of the Durom Cup.

94. Defendants breached their duty of reasonable care to Plaintiff by defectively designing, manufacturing, and/or negligently failing to warn of these defects in the Durom Cup, thereby causing Plaintiff' injuries and damages.

95. Defendants breached their duty of reasonable care to Plaintiff by manufacturing and assembling the Durom Cup in such a manner that it was prone to failures and malfunction and thus exposed Plaintiff Tony Brown to severe and lasting physical trauma and injuries.

96. Defendants breached their duty of reasonable care to Plaintiff by failing to promptly and adequately notify the FDA and warn and instruct Plaintiff, the medical community, and the public at the earliest possible date of known defects in the Durom Cup. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

97. Defendants' conduct, as described above, was reckless in that Defendants were aware of, yet consciously disregarded, a substantial and unjustifiable risk that Durom cup users, including Plaintiff Tony Brown, would suffer serious injury or death as a result of Defendants' defective design and manufacture of the Durom cup, as well as Defendants' failure to warn of these defects. This disregard constituted a gross deviation from the standard of care that an ordinary person would have exercised under the circumstances, warranting the imposition of punitive damages against Defendants.

98. As a direct and proximate result of Defendants' wrongful misconduct, Plaintiff have sustained and will continue to sustain severe physical injuries, severe emotional distress,

mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT V
(Negligence *Per Se*)

99. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

100. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Durom Cup, and otherwise distributing the Durom Cup.

101. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se.*

102. Plaintiff, as a purchaser of the Durom Cup, are within the class of persons the statutes and regulations (described above) are designed to protect and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

103. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VI
(Breach Of Implied Warranty)

104. Plaintiff hereby incorporate by reference all preceding paragraphs as if

fully set forth herein.

105. Defendants impliedly warranted that the Durom Cup, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiff and their physicians, was merchantable and fit and safe for ordinary use.

106. Defendants further impliedly warranted that the Durom Cup, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiff and their physicians, was fit for the particular purposes for which it was intended and was sold.

107. Contrary to these implied warranties, the Durom Cup was defective, unmerchantable, and unfit for its ordinary use when sold, and unfit for the particular purpose for which it was sold.

108. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VII
(Breach Of Express Warranty)

109. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

110. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the Durom Cup was safe, effective, fit and proper for its intended use.

111. In allowing the implantation of the Durom Cup, Plaintiff and their physician relied on the skill, judgment, representations, and express warranties of Defendants.

These warranties and representations were false in that the Durom Cup was not safe and was unfit for the uses for which it was intended.

112. Through sale ofthe Durom Cup, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

113. Defendants breached their warranty of the mechanical soundness of the Durom Cup by continuing sales and marketing campaigns highlighting the safety and efficacy of their product, while they knew or should have known of the defects and risk of product failure and resulting patient injuries.

114. As a direct and proximate result of Defendants' wrongful conduct, PlaintifTs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VIII
(Negligent Misrepresentation)

115. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

116. At the time Defendants manufactured, designed, marketed, sold and distributed the Durom Cup for use by Plaintiff, Defendants knew or should have known of the use for which the Durom Cup was intended and the serious risks and dangers associated with such use of the Durom Cups.

117. Defendants owed a duty to physicians and patients using the Durom Cup, including Plaintiff, to accurately and truthfully disclose the risks of the Durom Cup. Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiff

Tony Brown's physicians, the medical community, Plaintiff, and the public about the risks of the Durom Cup, which Defendants knew or in the exercise of diligence should have known.

118. As a direct and proximate result ofDefcndants' wrongful conduct, Plaintiff sustained and will continue to sustain severe physical injuries. severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial.

COUNT IX

(Intentional Misrepresentation)

119. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

120. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell the Durom Cup, owed a duty to provide accurate and complete information to Plaintiff, his physicians, and the public regarding the Durom Cup.

121. However, Defendants misled Plaintiff Tony Brown, his physicians, and the public into believing that the Durom Cup was safe and effective for use in hip replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince physicians and patients to use the Durom Cup, even though Defendants knew or should have known that the Durom Cup was unreasonably unsafe. Defendants also failed to warn physicians and the public about the safety risks of the Durom Cup and the Metasul implant system they designed, marketed and sold.

122. Defendants' advertising program and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Durom Cup was safe for human use, had no unacceptable side

effects, and would not interfere with daily life.

123. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of the Durom Cup. Defendants, through promotional practices as well as the publication of medical literature, deceived potential treating physicians, Plaintiff Tony Brown, other patients, and the public. Defendants falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including Plaintiff Tony Brown, regarding the safety of the Durom Cup.

124. Defendants expressly denied that the Durom Cup created an increased risk of injury and took at1irmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from the Durom Cup.

125. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, physicians, Plaintiff Tony Brown, and the public, the truth regarding Durom Cup failures for months, if not years, all the while undertaking a major advertising campaign to sell the Durom Cup. Defendants received reports of the Durom Cup defects from various sources, including Dr. Dorr, and intentionally withheld this information from physicians and patients, while continuing to sell the Durom Cup for implantation in individuals such as Plaintiff Tony Brown.

126. Further, even as Defendants eventually may have disclosed some information regarding the Durom Cup defects, any such disclosures were incomplete and misleading.

127. Defendants effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of the Durom Cup. The truth did

not begin to emerge until, at the earliest, May 2008 when Zimmer issued a "Dear Doctor" letter to physicians that suggested that Durom Cup defects were arising because of doctors' surgical techniques. This letter was inadequate and failed to fully inform physicians, patients, including Plaintiff Tony Brown, and the public of the true defects in the Durom Cup, defects that were known to Defendants. Even after the letter, Defendants' sales representatives continued to assure physicians and patients that the Durom Cup was adequate and reliable for the purpose intended and they continued to sell the Durom Cup.

128. Through the materials they disseminated, Defendants falsely and deceptively misrepresented or omitted a number of material facts regarding the Durom Cup.

129. Defendants possessed evidence demonstrating the Durom Cup was defective and likely to fail and injure patients. Nevertheless, Defendants continued to market the Durom Cup by providing false and misleading information with regard to its safety to Plaintiff Tony Brown and Plaintiff Tony Brown's physicians.

130. Defendants engaged in all the acts and omissions described above with the intent that Plaintiff Tony Brown's physicians and Plaintiff Tony Brown would rely on these misrepresentations, deception and concealment in deciding to use Defendants' Durom Cup rather than another Zimmer product or a competitors' similar product.

131. Plaintiff Tony Brown and Plaintiff Tony Brown's physicians justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations as set out above. This reliance proximately caused the injuries and damages described in this Complaint.

132. As a direct and proximate result of Defcndants' wrongful conduct, Plaintiff Tony Brown sustained and will continue to sustain severe physical injuries.

Plaintiff suffered and will continue to suffer severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory damages and in an amount to be proven at trial.

COUNT X
(Constructive Fraud)

133. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

134. At the time Defendants sold the Durom Cup to Plaintiff, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the Durom Cup, which knowledge was not possessed by Plaintiff Tony Brown or his physicians, and Defendants thereby held a position of superiority over Plaintiff.

135. Through their unique knowledge and expertise regarding the defective nature of the Durom Cup, and through their statements to physicians and their patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiff Tony Brown that they had knowledge of the truth of the representation that the Durom Cup was safe and effective for its intended use and was not defective.

136. Defendants' representations to Plaintiff, the medical community, and the public were unqualified statements made to induce Plaintiff and their physicians to purchase and use the Durom Cup; and Plaintiff Tony Brown and his physicians relied upon the statements prior to purchasing the device and having it implanted in Plaintiff Tony Brown's body.

137. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff Tony Brown and his physician and engaged in constructive fraud in their relationship with Plaintiff. Plaintiff Tony Brown and his

physicians reasonably relied on Defendants' representations.

138. As a foreseeable, direct and proximate result of Defendants' willful and wrongful conduct and reckless disregard for Mr. Brown's well-being, Plaintiff sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they arc entitled to compensatory, punitive and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT XI
(Negligent Infliction Of Emotional Distress)

139. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

140. Defendants carelessly and negligently manufactured, marketed and sold the Durom Cup to Plaintiff Tony Brown, carelessly and negligently concealed the Durom Cup defects from Plaintiff, and carelessly and negligently misrepresented the quality, safety and usefulness of the Durom Cup.

141. Plaintiff Tony Brown was directly involved in and directly impacted by Defendants' carelessness and negligence, in that Plaintiff Tony Brown has sustained and will continue to sustain severe physical injuries, economic losses, and other damages as a direct result of his (and his physicians') decision to purchase, use and have implanted in his hip a defective and dangerous product manufactured, sold and distributed by Defendants.

142. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered injuries, damages and harm detailed herein, for which they are entitled to compensatory damages in an amount to be proven at trial.

COUNT XIV
(Unjust Enrichment)

143. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

144. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' Durom Cup by Plaintiff Tony Brown.

145. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff were not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiff, as reasonable consumers, expected.

146. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

forth herein.

COUNT XV
(Punitive Damages)

147. All preceding allegations are incorporated by references as if fully set

148. The acts of Zimmer were willful and wanton, malicious, and showed a total disregard for human life and human suffering. Based upon the acts alleged herein, Zimmer knew or should have known, in light of the surrounding circumstances, that their conduct would naturally and probably result in injury and damage. Zimmer continued such conduct with malice and/or in reckless disregard of the consequences, from which malice may

be inferred. Tony Brown should be awarded punitive damages against Zimmer, based upon the acts herein so as to punish Zimmer and deter similar conduct.

RELIEF REQUESTED

WHEREFORE, Plaintiff pray for judgment against Defendants and in their favor and award additional relief as follows:

1. Economic and non-economic damages in an amount in excess of $150,000 as provided by law and to be supported by the evidence at trial;
2. For compensatory damages for the acts complained of herein in an amount to be determined by a jury;
3. Loss of consortium damages for the acts complained of herein in an amount to be determined by a jury;
4. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;
5. Punitive damages for the acts complained of herein in an amount to be determined by a jury;
6. For an award of attorneys' fees and costs;
7. For prejudgment interest and the costs of suit; and,
8. For such other and further relief as this Court may deem just and proper.

Respectfully submitted,

HOVDE DASSOW & DEETS, LLC

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JURY DEMAND

Tony Brown, by and through designated counsel, demands a trial by jury of all claims asserted in this complaint.

Dated: July 1, 2020

HOVDE DASSOW & DEETS, LLC

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